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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,572	04/21/2004	Steven A. McAuley	1001.1704101	5285
28075	7590	11/02/2005		
CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			EXAMINER BOUCHELLE, LAURA A	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/828,572

Applicant(s)

MCAULEY ET AL.

Examiner

Laura A. Bouchelle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/21/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/26/04, 8/15/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1 and 7, 8, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knorig (US 6264633) in view of Hart et al (US 6626861). Knorig discloses a balloon catheter comprising a catheter 10, a balloon 11, a guidewire lumen 18, and an inflation lumen 25, wherein the balloon has undulations that serve as gripping surfaces 12 to cling to the surfaces adjacent to the balloon. See Fig. 1.

3. Claims 1, 13, 25, 33-35 differ from Knorig in calling for the catheter to have a traction member. Claims 8, 21, and 28 call for the traction member to have a second end coupled to the balloon catheter. Claim 11 calls for the traction member to be coupled to the shaft. Claims 12 calls for the traction member to be coupled to the balloon. Hart discloses a balloon catheter comprising a traction member 36 with a gripping surface that provides traction within a vascular conduit or other passageway (Col. 2, lines 38-43). Further the proximal end 38 of the traction sleeve 36 is connected to the distal end 16 of the catheter tube 12, and the distal sleeve end 40 is connected to the distal end of the balloon (Col. 6, lines 59-64). Therefore, it would have been

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obvious to one of ordinary skill in the art at the time of invention to modify the balloon catheter of Knorig to include a traction sleeve with a gripping surface as taught by Hart so that the balloon has traction within the vascular conduit.

4. Claim 35 differs in calling for a method comprising the steps of advancing the catheter through a blood vessel and inflating the balloon. Hart discloses a method including the steps of providing a balloon catheter (Col. 11, lines 36-37), inserting the balloon catheter into the vascular conduit adjacent the obstructing material (Col. 11, lines 43-46) and inflating the balloon such that it is radially expanded sufficiently to contact the inner walls of the vascular conduit (Col. 11, lines 54-56). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Knorig to include the steps of inserting the balloon catheter, and inflating the balloon as taught by Hart so that the balloon comes in sufficient contact with the vascular conduit to be treated.

5. Claims 22- 24, and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knorig in view of Hart et al. Claims 22- 24, and 29-32 differ from the teachings above in calling for the proximal end of the traction member to be disposed at either the proximal waist, the midpoint, or the distal waist of the balloon. At the time the invention was made, it would have been an obvious matter of design choice to have the proximal end of the traction member disposed at any of the above stated locations. Applicant has not disclosed that having the proximal end of the traction member disposed in a specific location serves any advantage or particular purpose or solves a stated problem. Furthermore, one of ordinary skill would expect

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the device of Knorig in view of Hart to perform equally well with the proximal end of the traction member disposed at any of the stated locations. Therefore, it would have been prima facie obvious to modify Knorig in view of Hart to obtain the invention as specified in claims 22-24, and 29-32 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Knorig in view of Hart.

6. Claims 2 and 15, and 6 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knorig in view of Hart et al as applied to claims 1 and 13 above, and further in view of Mareiro et al (US 6258099). Claims 2 and 15 differ from the above teachings in calling for the gripping surface to be bumps. Claims 6 and 19 call for the gripping surface to be spikes. Mareiro discloses a balloon catheter having a gripping surface comprising bumps (Fig. 5e) or spikes (Fig. 5c) to increase the retention characteristics of the balloon (Col. 4, lines 56-57). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the balloon catheter of Knorig in view of Hart to include gripping surfaces that are either bumps or spikes as taught by Mareiro to increase the retention characteristics of the balloon within the conduit.

7. Claims 3 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knorig in view of Hart et al as applied to claims 1 and 13 above, and further in view of Bradshaw (US 6450988). Claims 3 and 16 differ from the above teachings in calling for the gripping surface to be defined by a helical region. Bradshaw discloses a balloon catheter, wherein the balloon comprises a region of helical lobes 26 with protruding knobs 30 that engage the vessel wall while

allowing for a perfusion channel (Col. 4, lines 40-47). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the gripping member of Knorig in view of Hart to be of a helical shape as taught by Bradshaw so that the balloon engages the wall of the vessel while allowing for perfusion through the channel.

8. Claims 4 and 17, and 5 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knorig in view of Hart et al as applied to claims 1 and 13 above, and further in view of Grayzel et al (US 2002/0010489). Claims 4 and 17 differ from the above teachings in calling for the gripping surface to be defined by a ridge along the body portion. Claims 5 and 18 call for the gripping surfaces to be defined by saw tooth projections. Grayzel discloses a balloon catheter comprising gripping member in the shape of a ridge 46 or alternatively in the shape of saw tooth projections 500. See Figs. 2 and 9G. These configurations facilitate the dilation of the target lumen by the expanding balloon (Page 4, paragraph 0053). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the gripping surfaces of Knorig in view of Hart to be either a ridge or saw tooth projections as taught by Grayzel to facilitate the dilation of the target lumen by the expanding balloon.

9. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Knorig in view of Hart et al as applied to claim 9 above, and further in view of Campbell (US 5928193). Claim 10 differs from the teachings above in calling for the guidewire to extend distally out the end of the guide lumen. Campbell discloses a balloon catheter wherein the guidewire 82 extends through the lumen and past the balloon for rapid exchange of the guidewire (Col. 5, lines 1-4). See Figs.

7 and 8. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the balloon catheter of Knorig in view of Hart such that the guidewire extends past the distal end of the guide lumen as taught by Campbell to allow for rapid exchange of the catheter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura A Bouchelle
Examiner
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